USER MANUAL

Jaundice Meter (JM-103)

From Konica Minolta and Hill-Rom Air-Shields

Hill-Rom Air-Shields
A HILLENBRAND INDUSTRY

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Section 1
Symbol Definition and Intended Use

Symbol Definition

This manual contains different typefaces and icons designed to improve readability and increase understanding of its content. Note the following examples:

- Standard text—used for regular information.
- **Boldface text**—emphasizes a word or phrase.
- **NOTE:**—sets apart special information or important instruction clarification.
- The symbol below highlights a WARNING or CAUTION:

Warning and Caution

  - A WARNING identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.
  - A CAUTION points out special procedures or precautions that personnel must follow to avoid equipment damage.

- The symbol below highlights a type BF applied part:

Type BF Applied Part

  - The instrument provides a specified degree of protection against electric shock, particularly the leakage current and reliability of the protective ground connection with an F-type applied part. An F-type applied part indicates an applied part isolated from all other parts of the instrument to such a degree that the patient leakage current allowable in a single-fault condition is not exceeded when a voltage equal to 1.1 times the highest-rated mains voltage is applied between the applied part and ground.

- The symbol below highlights an ELECTRICAL SHOCK HAZARD WARNING:

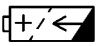
Electrical Shock Hazard Warning

- The symbol below indicates INPUT RATING:

Input Rating Symbol

- The symbol below indicates that the product uses a RECHARGEABLE BATTERY:

Rechargeable Battery Symbol



- The symbol below indicates RESET:

RESET Button Symbol

- The symbol below, when applied to the device, indicates:

ATTENTION: Consult Accompanying Documents

Intended Use

Indications for the Use of the Jaundice Meter (JM-103)

The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants and displays a measured value which has been shown to correlate with serum bilirubin. The device is for use in the hospital to assist clinicians in monitoring the status of newborn infants for the development of hyperbilirubinemia. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements. Newborn infants whose Jaundice Meter (JM-103) test results are indicative of hyperbilirubinemia are evaluated by their doctor(s) for appropriate patient management. Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

Intended Use of the User Manual

This manual provides instructions for installation, use, operator maintenance, and troubleshooting of the Jaundice Meter (JM-103) from Konica Minolta and Hill-Rom Air-Shields. Konica Minolta/Hill-Rom Air-Shields cannot be responsible for the performance of the Jaundice Meter if the user does not operate the unit in accordance with the instructions, fails to follow maintenance recommendations, or makes any repairs with unauthorized components. Only qualified service personnel should perform repair. Service information is available through your local distributor or Konica Minolta/Hill-Rom Air-Shields.

NOTES:

Section 2
Introduction, Features, and Specifications

Introduction

To prevent kernicterus in newborn infants, it is very important to detect jaundice in its early stages. The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. This hand-held device allows a quick, non-invasive estimate of bilirubin concentration, to be used as an aid for the management of jaundice in newborn infants. The measurements are taken automatically when you place the instrument's measuring probe against the forehead or sternum of the infant and press it gently; the measured value is then displayed.

The Jaundice Meter (JM-103) measures the yellowness of the subcutaneous tissue in infants through the detection of the optical density difference at two wavelengths. It displays a measured value that has been shown to correlate with serum bilirubin. The device is intended for use in the hospital to assist clinicians in monitoring the status of infants for the development of hyperbilirubinemia. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements. Infants whose Jaundice Meter (JM-103) test results are indicative of hyperbilirubinemia are evaluated by their doctor(s) for appropriate patient management. Bilirubin levels should be confirmed by other methods (e.g. serum bilirubin) prior to treatment determinations.

Measuring Point

Measurements must be taken only on the infant's forehead or sternum where a sufficient amount of blood is circulated. A possibility exists that the bilirubin in the subcutaneous tissue may measure low for areas with minimal blood flow or areas in which the subcutaneous tissue is subject to keratinization.

The measuring points for this device include the forehead and the sternum of the infant. Although correlation with serum bilirubin was observed for both forehead and sternum measurements, the clinical studies performed with the Jaundice Meter (JM-103) show consistently better results with measurements taken at the sternum versus the forehead.

Precocious Jaundice

Do not use this device on infants with precocious jaundice. If there is a possibility that the infant is suffering from precocious jaundice, as a result of an incompatible blood type or hemolytic jaundice, it is recommended that the total serum bilirubin be measured.

Phototherapy

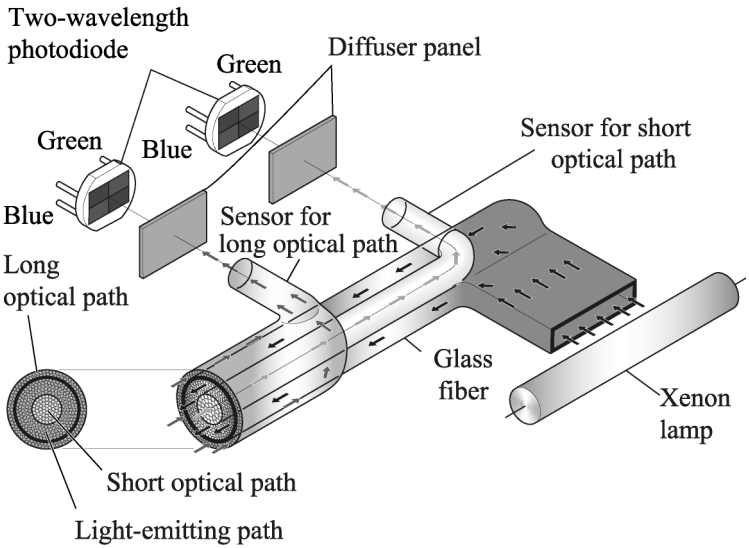
⚠ WARNING:

Do **not** use the Jaundice Meter after initiation of phototherapy or after an exchange transfusion. Patient injury could occur.

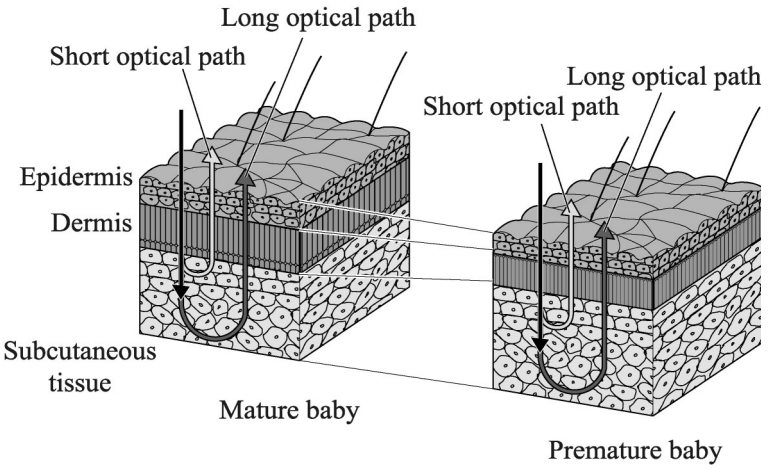
Explanation of the Test

Measuring Principle

The Jaundice Meter determines the yellowness of an infant's subcutaneous tissue by measuring the difference in the optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring probe has two optical paths. This method allows for a more precise measurement of yellowness in an infant's subcutaneous tissue by minimizing the influences of the melanin pigment and the skin maturity.



When the measuring probe is pressed against the forehead or sternum of the infant, the built-in xenon lamp flashes. The light from the xenon lamp passes through the glass fiber and illuminates the skin. The light scatters and is absorbed in the skin and subcutaneous tissue repeatedly, and then finally returns to the sensor side of the glass fiber. Of the light that returns, the part scattered from the shallow areas of the subcutaneous tissue passes through the inner core, or short-optical path, of the fiber. The part scattered from the deep areas of the subcutaneous tissue passes through the outer core, or long-optical path, and then reaches its corresponding photodiode.



By calculating the difference in the optical densities, the parts that are common to the epidermis and dermis are deducted, and as a result, the difference in the optical densities between the two wavelength regions can be obtained for the subcutaneous tissue only. Since the optical density difference shows a linear correlation with the total serum bilirubin concentration, it is converted to the estimated bilirubin concentration and is indicated digitally.

The Jaundice Meter (JM-103) device software uses a correlation coefficient to convert the measurement difference from the dual optical path to an estimated bilirubin concentration. The calculation formula used includes the correlation coefficients α and γ. These coefficients were determined in pre-clinical testing. The equation used is as follows:

$$J_{sample} = \alpha(L-S) + \gamma$$

Where L and S are the long and short optical path measurements.

Use of the Device

Patient Population

The Jaundice Meter (JM-103) is indicated for use in neonatal patients born >35 weeks gestation who have not undergone transfusion or phototherapy treatment.

Averaging of Measurements

There was no significant difference between the averaged measurements and the single measurement approaches in the largest study for sternum measurements. The mean of three measurements showed the highest degree of correlation (r=0.965), however, the difference was minimal with a single measurement (r=0.963).

The advantages of using average measurements should be assessed at each facility.

Action Levels

Each facility should determine their own action levels based on studies of performance of the device on their population. Appropriate action levels may vary depending on performance of the device, such as precision or correlation with serum bilirubin, in the hands of the user. Some factors that could affect performance of the device or appropriate action levels include skin color, age, or measurement site. Careful selection of action levels should be made so that false negatives do not prevent appropriate follow up measures.

Calibration

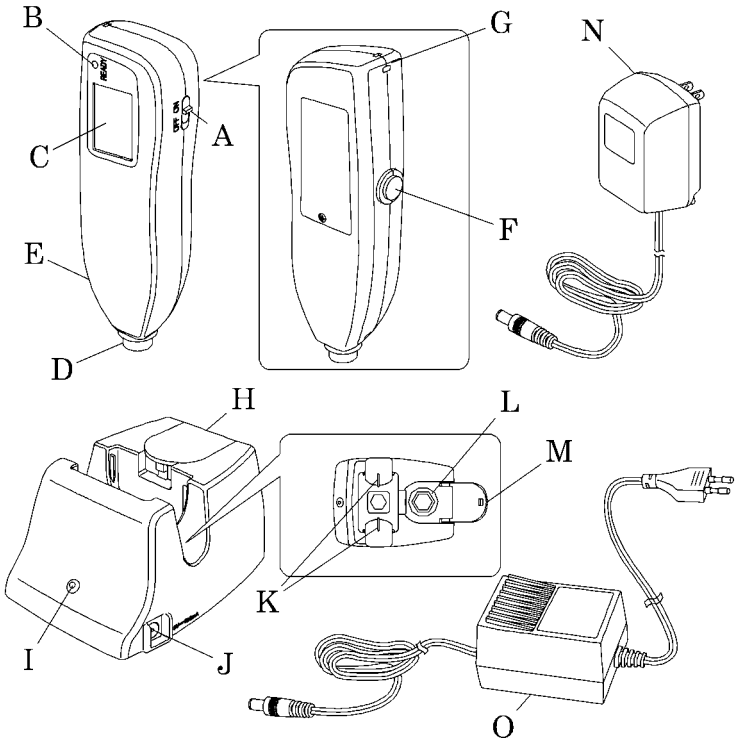
There is no user calibration of this device. The system does include a checker that measures the intensity of light from the device to ensure the light output is within range.

Processing of Measured Values

The Jaundice Meter (JM-103) determines the yellowness of the subcutaneous tissue by measuring the difference in the optical densities for light in the blue and green wavelength regions. The optical density difference has been shown to have a linear correlation with serum bilirubin concentration. The device computes an estimated bilirubin concentration based on this linear correlation and provides the value on the display. The correlation coefficient used in this computation was derived from clinical data.

Features

Controls, Indicators, and Connections

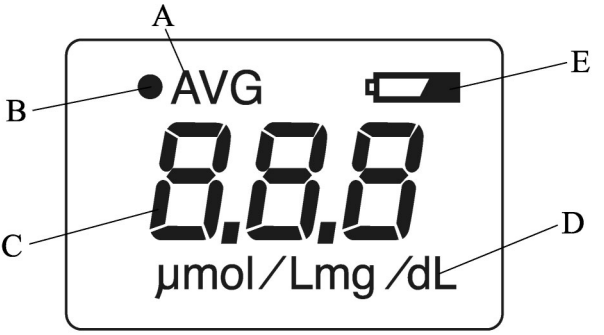


Controls, Indicators, and Connections

	Name	Function
A	**Power** switch	Turns the Jaundice Meter on and off. When used with the **Reset** button, the device switches to Check Mode and changes the unit of measurement.
B	**Ready** lamp	Illuminates to indicate that the Jaundice Meter is ready for the next measurement.
C	Display	Displays the measured value.
D	Measuring probe	Takes the measurement when pressed against the measuring point.

	Name	Function
E	Charger section	Connect the charger unit to the charger section.
F	**Reset** button	Deletes the currently displayed measured value and prepares for the next measurement. When used with the **Power** switch, the device switches to Check Mode and changes the unit of measurement.
G	Strap attachment area	Is where the strap attaches.
H	Checker cover	Open this checker cover to check the Jaundice Meter.
I	Charger lamp	Illuminates to indicate that the Jaundice Meter is charging.
J	DC jack	Connect the AC adapter to this jack.
K	Charger jack	Connect the main body to this jack.
L	Checker	Checks for the intensity of light output by taking measurements in Check Mode.
M	Standard checker values	For reference.
N	DC plug	Connect the charger's DC jack to this.
O	DC Plug (international)	Connect the charger's DC jack to this.

Display



	Name	Function
A	AVG	Illuminates during averaging measurement.
B	Optical path indicator (•)	When performing inspections with the checker, • illuminates when the L-value appears and extinguishes when the S-value appears.
C	Value	Displays the measured value. **NOTE**: When the measured value is greater than 20 mg/dl, the display shows "---" and the physician should be contacted.
D	Unit of measurement	Displays the unit of measurement in either milligrams per deciliter (mg/dL) or micro-moles of solute per liter (µmol/L)
E	Battery indicator 	When the battery power is low, the battery indicator blinks. Charge the battery as soon as possible (see "Charging the Battery" on page 4-1). If **only** the battery indicator lights, the battery has run out. Go to "Charging the Battery" on page 4-1. If the power is on and the display is blank, the battery is completely exhausted. Go to "Charging the Battery" on page 4-1.

Standard Features

- Jaundice Meter (JM-103)
- Charger unit (Model JM-A30) with a checker
- AC adapter (Model JM-A31)

Specifications

Standard Features

Feature	Dimension
Model name	JM-103
Measuring method	Determines the yellowness of the subcutaneous tissue by using two optical paths to measure the optical density difference at two wave-lengths
Measurement range	0.0 mg/dL to 20 mg/dL or 0 µmol/L to 340 µmol/L
RMSE *	± 1.5 mg/dL or ± 25.5 µmol/L
Light source	Pulse xenon arc lamp
Light source life	150000 measurements
Sensors	Silicon photodiodes
Power source	Special Ni-MH battery
Protection type and level	Internally-powered instrument, BF-type
Minimum number of measurements when fully charged	400 single measurements
Operating temperature range	10°C (50°F) to 40°C (104°F)
Operating relative humidity range	30% to 95%
Storage temperature range	-10°C (14°F) to 50°C (122°F)
Storage relative humidity range	30% to 95%
Dimensions	48 mm (1.9") wide x 15.5 cm (6.1") high x 33 mm (1.3") deep
Weight, including battery	150 g (5.3 oz)
AC adapter input for North America	120V, 50/60 Hz, 10 W
AC adapter input for International use	200V-240V, 50/60 Hz, 12.5VA
AC adapter output	9V, 500 mA

* This accuracy is based on the aggregate results from both clinical study groups (n=613). Refer to Appendix A for a detailed description of results by clinical site, measurement location, and patient demographics.

Regulations, Standards, and Codes

In North America
With respect to electrical shock, fire, and mechanical hazards only, this instrument complies with UL 2601-1 and CAN/CSA C22.2 No. 601.1.

In Europe, this instrument complies with EN60601-1, EN60601-1-2, and EN ISO13485, and EN ISO14971.

NOTES:

Section 3
Precautions and Safety Tips

Precautions

WARNING:

Do not use the instrument in areas where flammable or combustible gases, such as anesthetic gases, are present. Doing so could result in a fire. Personal injury or equipment damage could occur.

WARNING:

If the instrument, the charger unit, or the AC adapter are damaged, or if smoke or an odd smell occurs, do **not** use the instrument, the charger unit, or the AC adapter. In such situations, immediately turn off the instrument, unplug the AC adapter from its power source, and contact the nearest authorized service facility. Failure to do so could result in fire, personal injury, or equipment damage.

SHOCK HAZARD:

Always plug the instrument into an AC outlet of the correctly rated voltage and frequency. Failure to do so could result in fire, personal injury, or equipment damage.

SHOCK HAZARD:

Do not disassemble or modify the instrument, the charger unit, or the AC adapter. Fire, personal injury, or equipment damage could occur.

CAUTION:

Do not use a mobile telephone when using the Jaundice Meter. A measurement error could occur.

CAUTION:

The Jaundice Meter interferes with Magnetic Resonance Imaging (MRI) procedures. Inaccurate readings could occur.

CAUTION:

Do not place the instrument on an unstable or sloping surface. The instrument or charger unit could drop or overturn. Equipment damage could occur.

CAUTION:

The Jaundice Meter is a precision instrument. When using it, do **not** drop it, expose it to shocks or strong vibrations, or place heavy objects on it. Equipment damage could occur.

CAUTION:

Do not allow blood or other liquids to come in contact with the instrument. Should blood or other liquids come in contact with the instrument, immediately clean the instrument (see “Cleaning” on page 6-1). Failure to do so could result in equipment damage.

CAUTION:

Do not use the instrument in direct sunlight. Equipment damage could occur.

CAUTION:

The instrument has a built-in, non-replaceable battery. Do **not** disassemble the instrument to replace the battery. To replace the battery, contact your dealer or authorized Hill-Rom service center. Failure to do so could result in equipment damage.

Safety Tips

WARNING:

This instrument emits intense light to take its measurements. Take measurements only at the forehead or sternum, and do not press the measuring probe when it is directed toward the eyes. Damage to the eyes could occur.

WARNING:

Before use, clean the measuring probe by wiping it with medicinal alcohol. Failure to do so could result in the spread of infection or infant injury.

WARNING:

The charger unit (JM-A30) and the AC adapter (JM-A31) are solely designed for use with the Jaundice Meter (JM-103). Use them **only** when charging the instrument. Using them to charge other equipment could result in personal injury or equipment damage.

WARNING:

Only facility-authorized personnel should troubleshoot the Jaundice Meter. Troubleshooting by unauthorized personnel could result in personal injury or equipment damage.

WARNING:

Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.

WARNING:

Do **not** use the Jaundice Meter after initiation of phototherapy or after an exchange transfusion. Patient injury could occur.

SHOCK HAZARD:

Do not plug or unplug the AC power cord's plug with wet hands. Personal injury or equipment damage could occur.

SHOCK HAZARD:

Before cleaning, maintenance, or parts replacement, unplug the charger unit from its power source. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

CAUTION:

Do not use harsh cleansers/detergents, such as scouring pads and heavy duty grease removers, or solvents, such as toluene, xylene, and acetone. Equipment damage could occur.

Warning and Caution Labels

⚠WARNING
RISK OF FIRE: DO NOT USE THIS INSTRUMENT IN PLACE WHERE CONBUSTIBLE GASES (ANESTHETICS,ETC.) ARE PRESENT.
RISK OF ELETRIC FIRE: DO NOT MODIFY OR DISASSEMBLE THIS INTRUMENT.
⚠CAUTION
HIGH INTENSITY FLASH. USE ONLY ON RECOMMENDED SKIN LOCATION.

Section 4
Installation and Assembly

Installation

Before using the instrument, charge and inspect the instrument.

Charging the Battery

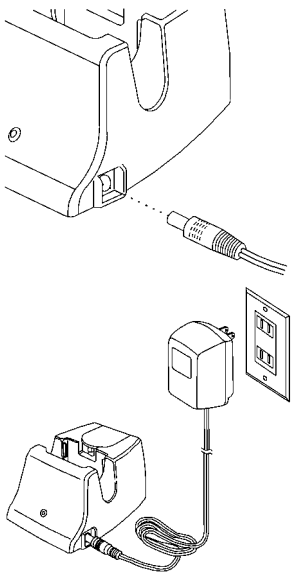
When using the instrument for the first time, ensure that it is fully charged. To maintain a full charge at all times, place the instrument on the charger unit when it is not being used for measurements. When the battery power is low, the **Battery** display blinks.

If the Jaundice Meter is left uncharged for a long period of time, the power of the battery diminishes; ensure that it is charged prior to use. To charge the Jaundice Meter, perform the following:

⚠ WARNING:

The charger unit (Model JM-A30) and the AC adapter (Model JM-A31) are solely designed for use with the Jaundice Meter (JM-103). Use them **only** when charging the instrument. Using them to charge other equipment could result in personal injury or equipment damage.

1. Plug the AC adapter into the **DC** jack of the charger unit. Use only the charger unit and AC adapter supplied with the Jaundice Meter.



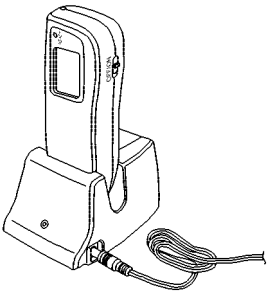
NOTE:
The shape of the AC adapter varies according to region.

NOTE:
120V model shown.

SHOCK HAZARD:

Do not plug or unplug the AC power cord's plug with wet hands. Personal injury or equipment damage could occur.

2. Plug the AC adapter's plug into an AC outlet. Never do so with wet hands.
3. Place the Jaundice Meter on the charger unit so that its display faces you. When the Jaundice Meter is set on the charger unit properly, the **Charger** lamp lights up.



NOTE:
With a fully charged battery, approximately 400 measurements can be taken. With six hours worth of charging, approximately 100 measurements can be taken.

4. Allow approximately 32 hours for charging to complete.

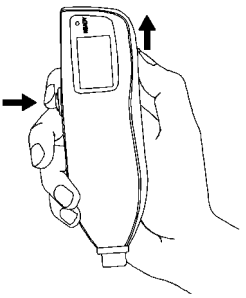
CAUTION:

The instrument has a built-in, non-replaceable battery. Do **not** disassemble the instrument to replace the battery. To replace the battery, contact your dealer or authorized Hill-Rom service center. Failure to do so could result in equipment damage.

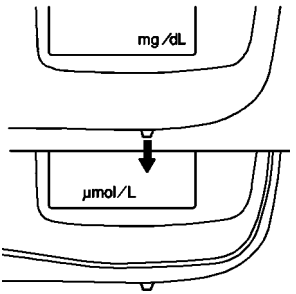
5. To replace the battery, contact your dealer or an authorized service facility.

Selecting the Unit of Measurement

1. Hold down the **Reset** button, and turn on the **Power** switch.Do not release the **Reset** button.



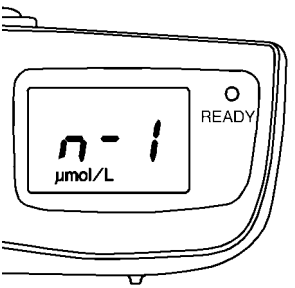
2. While continuing to press the **Reset** button, allow approximately 15 seconds for the unit of measurement to switch from mg/dL to µmol/L, or vice versa.



3. Visually ensure that the unit's display has changed.

4. Release the **Reset** button. The **Ready** lamp lights up, indicating that the instrument is ready to take a measurement.

5. To change the unit of measurement once more, turn off the **Power** switch, and repeat step 1.

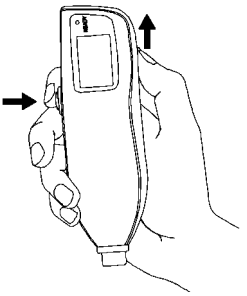


Operational Checkout of the Jaundice Meter

Do not touch the checker's surface with your fingers. If the checker gets dirty, wipe it with a soft cloth dampened with water, and then wipe it with a dry cloth.

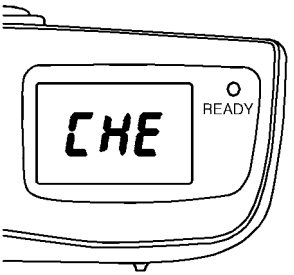
Using the checker supplied with the charger unit, check the instrument to ascertain that the meter light output is within range. Check the instrument **once or more** each day it is used. To inspect the Jaundice Meter, perform the following:

1. Hold the **Reset** button down, and set the **Power** switch to the **On** position.



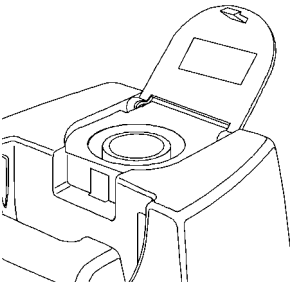
NOTE:
If the **Reset** button is held down for longer than 15 seconds, the unit of measurement switches.

2. After **CHE** appears on the display window, immediately release the **Reset** button. If the **Reset** button is held down for longer than 15 seconds, switch the unit of measurement back to its previous setting (see "Selecting the Unit of Measurement" on page 4-3).

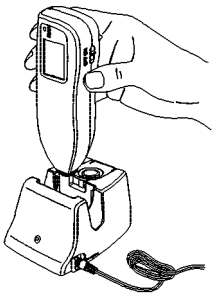


3. Visually confirm that **CHE** appears in the display and that the **Ready** lamp illuminates.

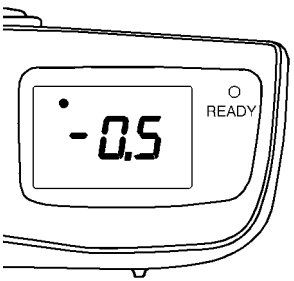
4. Open the cover of the checker. Use only the checker supplied with the Jaundice Meter (JM-103).



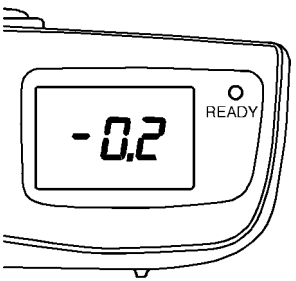
5. Place the measuring probe perpendicular to the checker, and push it gently until a click sounds.
6. If the measuring probe contacts the checker at an angle, place it perpendicular, and take the measurement again.



NOTE:
The display interchanges between the L-value, the measured value of the long-optical path, and the S-value, the measured value of the short-optical path. When the L-value is displayed, "•" appears in the upper left-hand corner of the display.



7. Confirm the measured value. If both the L-value and the S-value are within ± 1.0 of the reference values indicated on the checker, the values are acceptable.
8. If the measured value exceeds ± 1.0 of the reference value, perform the following:
    a. Clean both the checker and the measuring probe.
    b. Place the measuring probe perpendicular to the checker, and push it gently until a click sounds.
    c. If the measured value still exceeds ± 1.0 of the reference value, contact the nearest authorized service facility.
9. Close the cover of the checker.
10. Set the **Power** switch to the **Off** position.

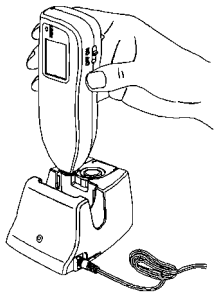


NOTES:

Instructions for Use

Taking Measurements

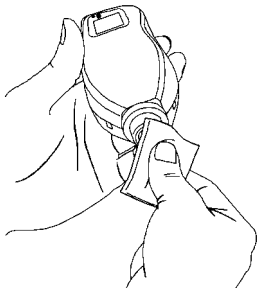
1. Remove the Jaundice Meter from the charger unit.



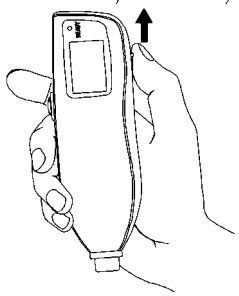
⚠ WARNING:

Before use, clean the measuring probe by wiping it with medicinal alcohol. Failure to do so could result in the spread of infection or infant injury.

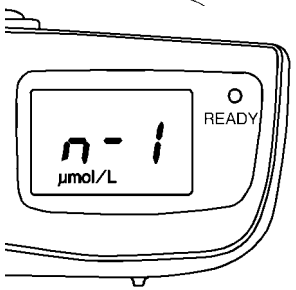
2. Using medicinal alcohol, clean the measuring probe.



3. Set the **Power** switch to the **On** position. The measured value for a single measurement, **n-1**, appears on the display.



4. Visually check that the **Ready** lamp illuminates.
5. If the battery indicator blinks, charge the battery (see "Charging the Battery" on page 4-1).

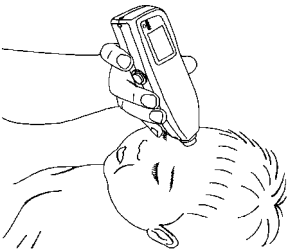


⚠ WARNING:

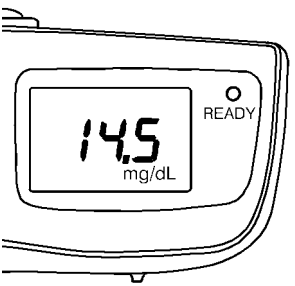
This instrument emits intense light to take its measurements. Take measurements only at the forehead or sternum, and do not press the measuring probe when it is directed to the eyes. Damage to the eyes could occur.

6. Perform the following:

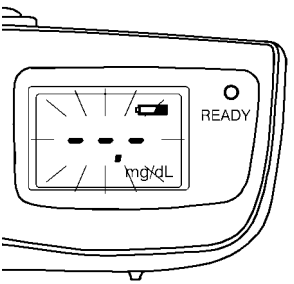
   a. Place the measuring probe vertically against the infant's forehead or sternum. Avoid any bruises or discolored areas of the skin.



   b. Push the measuring probe gently until a click sounds. The instrument's xenon lamp flashes momentarily, and the measured value appears on the display.



   • If the measured value is outside the measurement range of 20 mg/dL or 340 µmol/L, the display shows "---" and user should contact the physician.



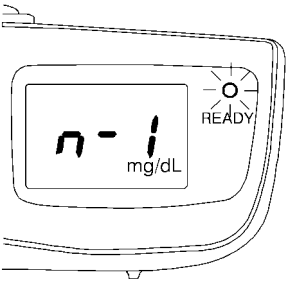
NOTE:
If the instrument is not operated for more than 60 seconds, the backlight on the display goes out.

7. To take another measurement, press the **Reset** button, and continue from step 4.

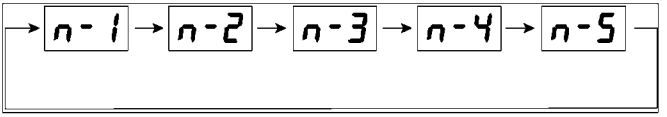
8. To stop measuring, perform the following:
    a. Set the **Power** switch to the **Off** position.
    b. Using medicinal alcohol, clean the measuring probe.
    c. Place the Jaundice Meter on the charger unit. When the Jaundice Meter is not in use, keep it on the charger unit.

Setting the Number of Average Measurements

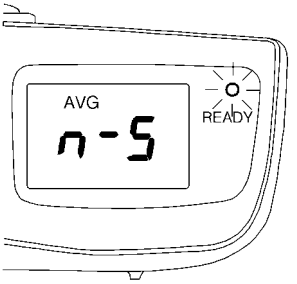
1. Set the **Power** switch to **On** or press the **Reset** button to prepare the instrument for measurement.
   - **n-1**, **n-2**, and so on (up to **n-5**) will appear.



2. Press the **Reset** button for 5 s. The number of average measurements will switch as follows:

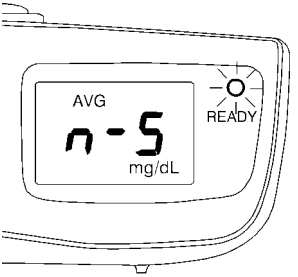


3. Release the **Reset** button when the required number of average measurements is displayed.
   - If **n-2** through **n-5** is selected, **AVG** appears in the upper left corner of the display.
   - The selected number of average measurements will be recorded.



Taking Average Measurements

1. Set the number of average measurements needed.
2. Ensure that the **Ready** lamp is illuminated once **n-5** appears.



NOTE:
n-5 is used in the steps below as an example. The number of measurements you require and set is the number that should appear in the display.

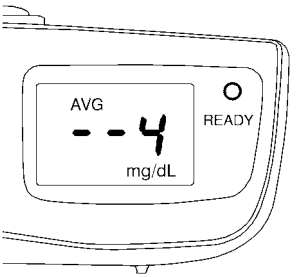
NOTE:
Each measurement must be taken individually by the user. The first measurement is complete when the measuring probe is pressed against the patient and the unit clicks. The probe must then be lifted from the patient and reapplied for the total number of measurements selected (in this example 5 measurements).

⚠ WARNING:

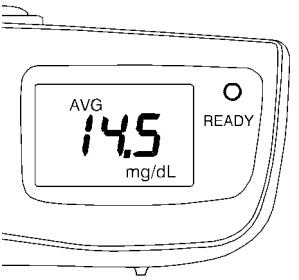
This instrument emits intense light to take its measurements. Take measurements only at the forehead or sternum, and do not press the measuring probe when it is directed toward the eyes. Damage to the eyes could occur.

NOTE:
It is recommended that all of the measurements taken for averaging be taken from the same measuring point, forehead or sternum.

3. Place the measuring probe vertically on the measuring point, and then apply gentle pressure until the probe clicks.
   - The measurement will be taken, and the number of remaining measurements will be displayed.



4. While ensuring that the **Ready** lamp is illuminated, repeat the measuring until the number of remaining measurements is 0.



- When the remaining number of measurements is completed, the average of the measured values appears in the display.
- If the instrument is left without the preset number of measurements taken, the setting will be canceled without the measurement value being displayed. To set the average measurements again, press the **Reset** button and reset the number of average measurements needed.
- To change the number of average measurements, refer to “Setting the Number of Average Measurements” on page 5-4.

Section 6
Cleaning, Maintenance, and Replacement Parts

Cleaning

WARNING:

Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

Before cleaning, maintenance, or parts replacement, unplug the charger unit from its power source. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

CAUTION:

Do not use harsh cleansers/detergents, such as scouring pads and heavy duty grease removers, or solvents, such as toluene, xylene, and acetone. Equipment damage could occur.

If there is no visible soilage with possible body fluids, we recommend that you clean the unit with a mild detergent and warm water. If disinfection is desired, you may use a combination cleanser/disinfectant as explained in "Disinfecting" on page 6-2.

Steam Cleaning

Do not use any steam cleaning device on the unit. Do not autoclave the unit. Excessive moisture can damage mechanisms in this unit.

Cleaning Hard to Clean Spots

To remove difficult spots or stains, we recommend that you use standard household cleansers and a soft bristle brush. To loosen heavy, dried-on soil, you may first need to saturate the spot.

Disinfecting

When there is visible soilage and between patients, we recommend that you disinfect the unit with a tuberculocidal disinfectant, such as Kleenaseptic B®. For customers in the US, the disinfectant should be registered with the Environmental Protection Agency.

Dilute the disinfectant according to the manufacturer's instructions, if necessary.

Maintenance

There are no user serviceable parts and no maintenance or calibration required. Service is only required if the unit ceases to function as intended or fails the checker reading (see "Operational Checkout of the Jaundice Meter" on page 4-4).

Replacement Parts

CAUTION:

The instrument has a built-in, non-replaceable battery. Do **not** disassemble the instrument to replace the battery. To replace the battery, contact your dealer or authorized Hill-Rom service center. Failure to do so could result in equipment damage.

There are **no** user-replaceable parts. To replace the battery, contact your dealer or an authorized service facility.

Section 7
Troubleshooting

Service Calls

When you call Hill-Rom about your unit, be prepared to give the serial number from the product identification label. When you give the serial number, the Hill-Rom representative can identify your unit and give you the information you need more quickly.

Error Messages

For warnings that may appear on the display window, refer to the table below.

Error Messages

Warning	Cause	Solution
Er1	The measured value is abnormal. In the case of an averaging measurement, the measurement fluctuation is excessively large.	Place the measuring probe perpendicular to the infant's forehead or sternum, and take the measurement again. If **Er1** still appears, contact the nearest authorized service facility.
Er2 through **Er6**	A measurement error may have occurred during an averaging measurement, or the hardware is not functioning properly.	Set the **Power** switch to the **Off** position, and then return it to the **On** position. If the warning still appears, contact the nearest authorized service facility.

Troubleshooting

⚠ WARNING:

Only facility-authorized personnel should troubleshoot the Jaundice Meter. Troubleshooting by unauthorized personnel could result in personal injury or equipment damage.

If an abnormality occurs with the Jaundice Meter, perform the following:

1. Refer to the table below, and take the necessary action given.
2. If the abnormality still appears, set the **Power** switch to the **Off** position, and then return it to the **On** position.
3. If the abnormality still continues, contact the nearest authorized service facility.

Troubleshooting

Symptom	Possible Cause	Action
The display is blank when the **Power** switch is in the **On** position.	The batteries are exhausted.	Charge the battery (see "Charging the Battery" on page 4-1).
The display suddenly goes blank during a measurement.	The batteries are exhausted.	Charge the battery (see "Charging the Battery" on page 4-1).
The **Charger** lamp does not illuminate when the Jaundice Meter is placed on the charger unit.	The charger unit and the AC adapter are not plugged into an AC outlet correctly.	Plug the charger unit and the AC adapter into an appropriate power source correctly.
	The Jaundice Meter is not placed in the charger unit correctly.	Place the Jaundice Meter perpendicular to the measuring point in the charger unit.
It is impossible to take measurements.	The **Ready** lamp is not illuminated.	Before taking a measurement, ensure that the **Ready** lamp is illuminated.
	The batteries are exhausted.	Charge the battery (see "Charging the Battery" on page 4-1).

Section 8
Storage and Handling

Storage and Handling

When storing the instrument, pay attention to the following conditions:

- Store the instrument at a temperature range of -10°C (14°F) to 50°C (122°F), and at a non-condensing relative humidity range of 30% to 95%.
- Keep the instrument dry.
- Do not store the instrument in locations that may have an adverse effect on its performance, such as locations subject to the following:
  - High atmospheric pressure
  - Direct sunlight—do not store near windows.
  - Extreme dust—do not store in closets or bins where dust or lint can gather.
  - Air having salinity or sulphur content
  - Strong magnetism—do not store near MRI or other imaging equipment, and do not store near operating rooms.
- Do not subject the instrument to vibration or impact.
- Do not store the instrument in locations where chemicals are stored or where gas may be emitted.
- To ensure no problems will exist the next time the main body and charger are used, thoroughly clean the main body and charger, and then store them together.

NOTES:

Warranty

HILL-ROM COMPANY, INC.
LIMITED WARRANTY

Hill-Rom Company, Inc. (Hill-Rom) has a long tradition of providing superior products and service to our customers. Our goal is "Total Customer Satisfaction". In that spirit, Hill-Rom is proud to offer the following warranty.

GENERAL WARRANTY (APPLICABLE UNLESS A SPECIFIC WARRANTY IS LISTED)

Hill-Rom warrants to the original purchaser that its products and replacement parts shall be free from defects in material and workmanship for a period of one (1) year from date of delivery. Hill-Rom's obligation under this warranty is expressly limited to supplying replacement parts and/or service for, or replacing, at its option, any product which is, in the sole discretion of Hill-Rom, found to be defective. In addition to the foregoing one year warranty, Hill-Rom warrants to the original purchaser that the frame and welds on its products will be free from structural defects for the life of the product. Any product upgrade or modification initiated by Hill-Rom does not affect the original product warranty.

SPECIFIC WARRANTIES

MATTRESS WARRANTIES

Hill-Rom warrants to the original purchaser that its mattress product shall be free from defects in material and workmanship for a period of two (2) years from date of delivery. However, electro mechanical mattress components (compressors, valves, printed circuit boards, hoses, and couplers) are covered by the general one (1) year warranty.

EXPENDABLES WARRANTIES

A sixty (60) day limited warranty from date of delivery applies to expendable parts such as cushions, coverlets, software diskettes, locator badge batteries, dome light incandescent bulbs, overhead fluorescent tubes, heating elements, temperature probes, filter sheets, and microspheres. This warranty is limited to replacement of the parts covered.

TO OBTAIN PARTS AND SERVICE

In the United States and Canada, call Hill-Rom Technical Support Department at (800) 523-5756, Monday through Friday. Outside the United States and Canada, call your authorized Hill-Rom Distributor. In order to expedite service, we request you furnish the following information: customer identification number, product model number, serial number, and description of problem. A qualified specialist will provide, via telephone (United States and Canada), or FAX (Outside the United States and Canada), troubleshooting assistance for facility personnel and provide necessary parts to make repairs. If troubleshooting determines the need for on-site technical service, a qualified service representative will be dispatched. Replacement of non-technical items will be the responsibility of the customer. If requested by Hill-Rom, products or parts for which a warranty claim is made shall be returned prepaid to Hill-Rom's factory.

OUT OF WARRANTY EXCHANGE POLICY

After the expiration of the original warranty, upon request, Hill-Rom will ship as a replacement, components such as selected: motors and printed circuit boards, for like units returned to Hill-Rom by the original purchaser at a substantial savings. Please call Hill-Rom Technical Support Department for current pricing.

PARTS AVAILABILITY POLICY

Hill-Rom will offer parts for new and remanufactured products for ten (10) years from date of sale; for communications products for five (5) years from date of sale.

Note: Some original component parts and assemblies may not be available; functional equivalents may be substituted.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE. HILL-ROM'S OBLIGATION UNDER THESE WARRANTIES SHALL NOT INCLUDE ANY LIABILITY FOR LOSS OF PROFITS, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES OR DELAYS. Some states, provinces, or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply. Any improper or negligent use, any alterations or repairs not in accordance with Hill-Rom's manuals or performed by others in such manner as in Hill-Rom's sole judgment affects the product materially and adversely, shall void these warranties. These warranties do not cover failures due to misuse, abuse, neglect, or lack of routine maintenance. No employee or representative of Hill-Rom is authorized to change these warranties in any way or grant any other warranty unless in writing and signed by a Hill-Rom officer. These warranties provide specific legal rights; but, there may be other available rights, which vary from state to state, province to province, or country to country.

Revised October 1, 2003

Hill-Rom Company, Inc., 1069 State Route 46 E, Batesville, IN 47006-9167

Appendix A
Clinical Performance Summary

Introduction

The Jaundice Meter (JM-103) has been the subject of three clinical studies. One study in Japan, the other two studies in the United States. The following information is a summary of results from the two US studies.

The purpose of the JM 103 is to measure the yellowness of subcutaneous tissue in the neonate. This measurement can be correlated to serum bilirubin concentration and is therefore an aid in the management of neonatal jaundice. Since this device performs measurement through the use of light it is non-invasive and painless for the infant. The objective of the clinical studies was to confirm that the device measurement, displayed in units of estimated bilirubin concentration, does correlate with the serum bilirubin concentration sufficiently well to warrant its use as a screening tool.

The following is a summary of the study protocols:

Selection Criteria

The patient selection criteria used for the study included infants less than 30 days old and weighing greater than 1000 grams. The test was performed on infants who were determined by their physician to require a serum bilirubin test. A tabulation of weight distribution is provided in graph 22 *Infant Weight Distribution*. Error plots by weight are provided in graphs 23 *Clinical Study Site A Birthweight Error Plot, Forehead* and 24 *Clinical Study Site A Birthweight Error Plot, Sternum*.

Demographics of Patient Population

All patients meeting the above criteria were included in the study. There was significant effort to ensure that there was sufficient representation of all skin pigmentation to verify that the JM 103 could be used across all populations with consistent results. The demographics of the patient population included Caucasian, African-American, and other.

Sample Size

The total number of infants in the sample population was 613.

Measurement Selection

One study followed a protocol where three measurements were taken, each measurement was recorded and then the three measurements were averaged. The second study took one measurement only. Estimated bilirubin measurements taken during the studies ranged from 1.1 to 20.8 mg/dL.

Body Sites Tested

In both studies the measurements were taken on the forehead and sternum each time the measurements were taken for a given patient.

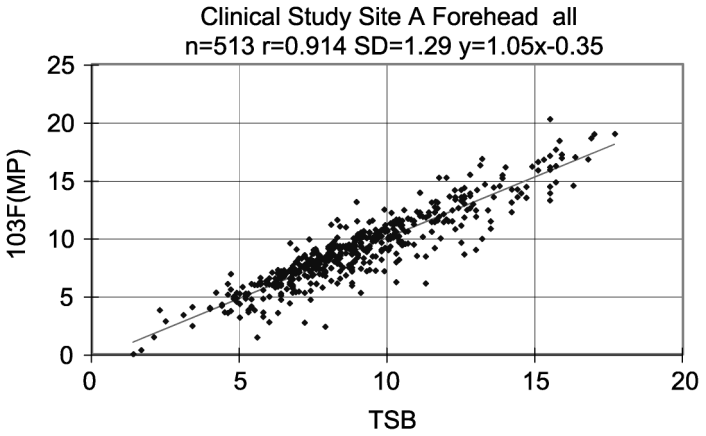
Number of Clinical Sites

There were two clinical sites that participated in the study. Clinical study site A with 513 patients studied. Clinical study site B with 100 patients studied.

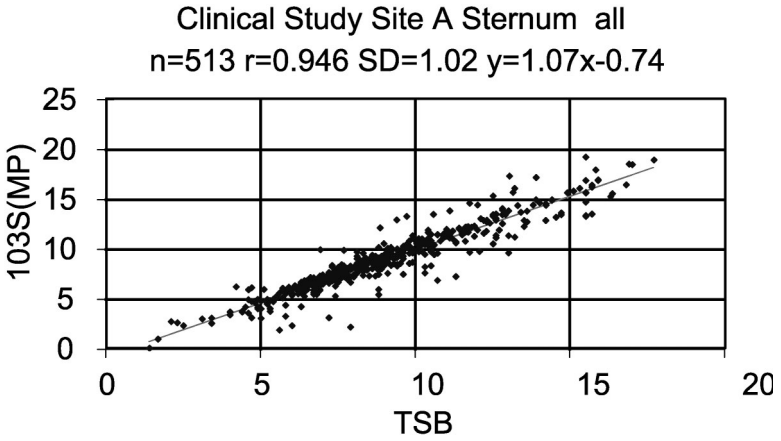
Performance Data

The following data is provided to demonstrate the performance of the JM 103 in the clinical use environment. This series of graphs show the correlation of the estimated bilirubin concentration taken non-invasively with the JM 103 to the actual serum bilirubin concentration measured from a blood sample taken from the patient (TSB). The device operates over a range of 0.0 – 20.0 mg/dL (0 – 340 μmol/L). The data include graphs in the form of x-y plots where x is the total serum bilirubin concentration measured and y is the JM 103 estimated bilirubin measurement. Forehead and sternum were not combined because the data would be too difficult to distinguish. The serum bilirubin measurements were taken using direct spectrophotometry in Clinical Study A and specifically with the Beakman-Colter Synchron LX-20by in Clinical Study B.

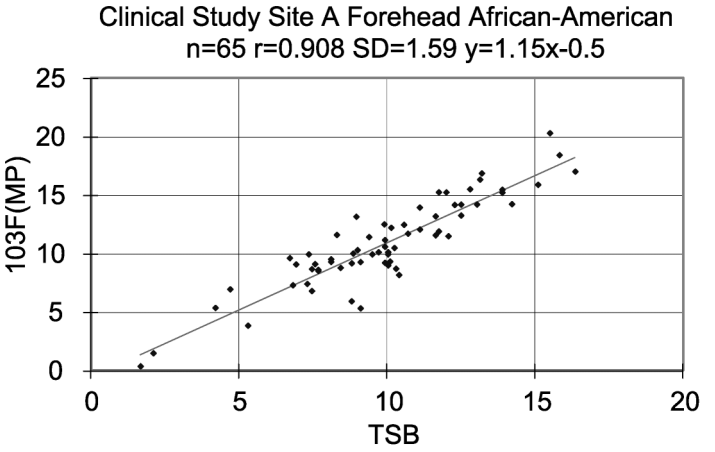
Graph 1 – Clinical Study Site A All Patients, Forehead



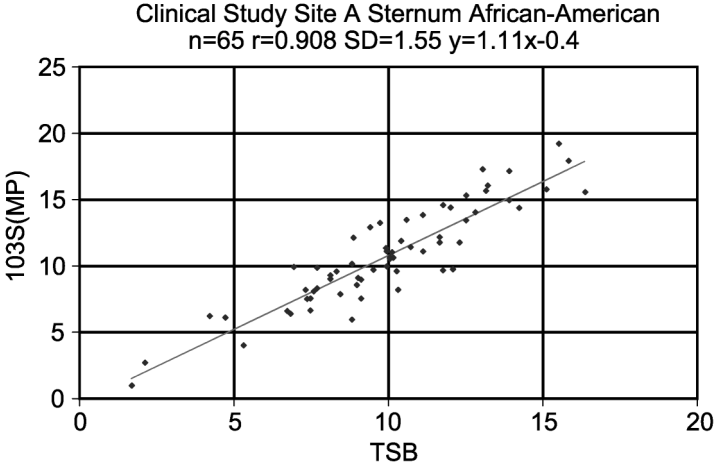
Graph 2 – Clinical Study Site A All Patients, Sternum



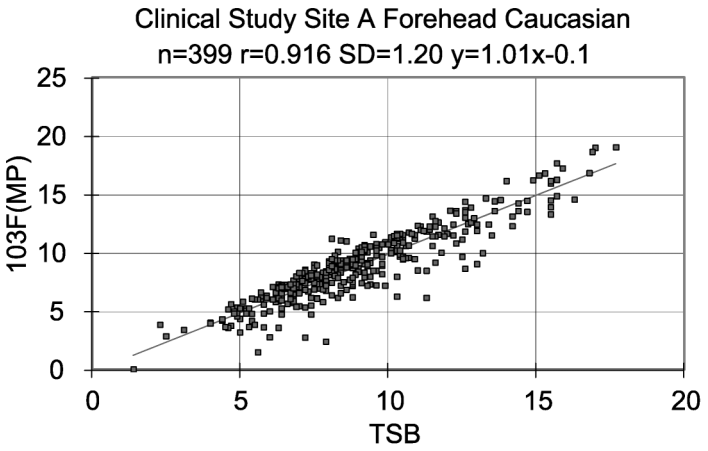
Graph 3 – Clinical Study Site A African-American Patients, Forehead



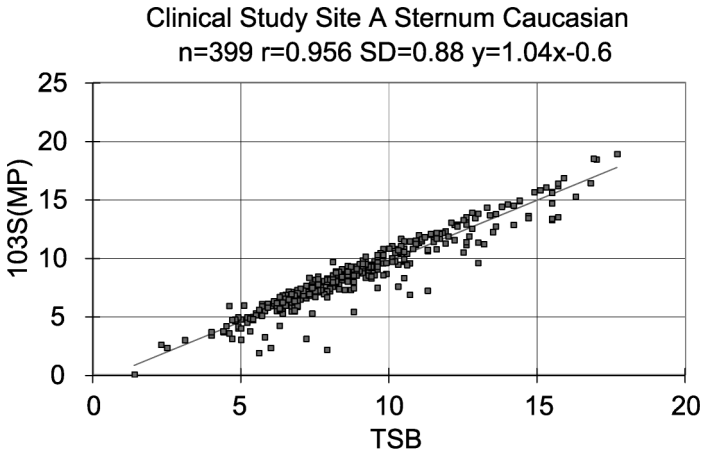
Graph 4 – Clinical Study Site A African-American Patients, Sternum



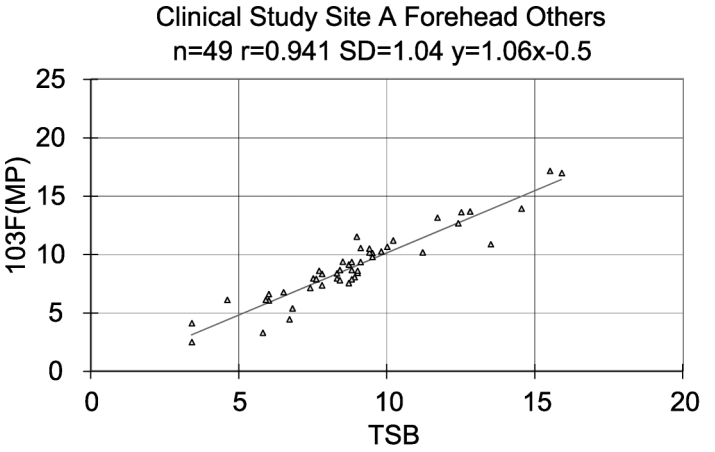
Graph 5 – Clinical Study Site A Caucasian Patients, Forehead



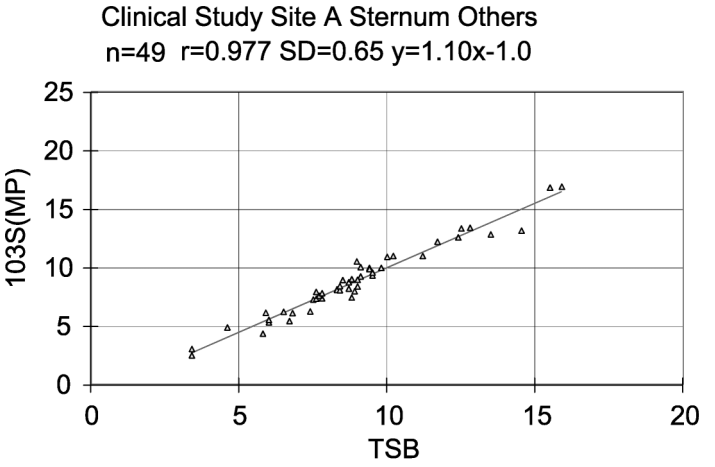
Graph 6 – Clinical Study Site A Causasian Patients, Sternum



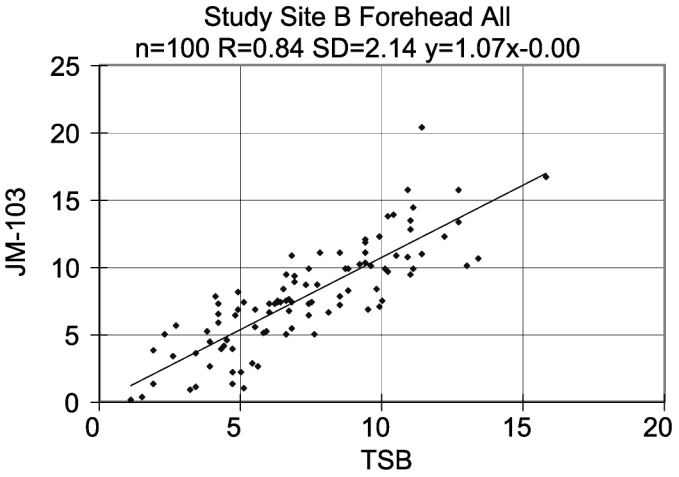
Graph 7 – Clinical Study Site A Other Patients, Forehead



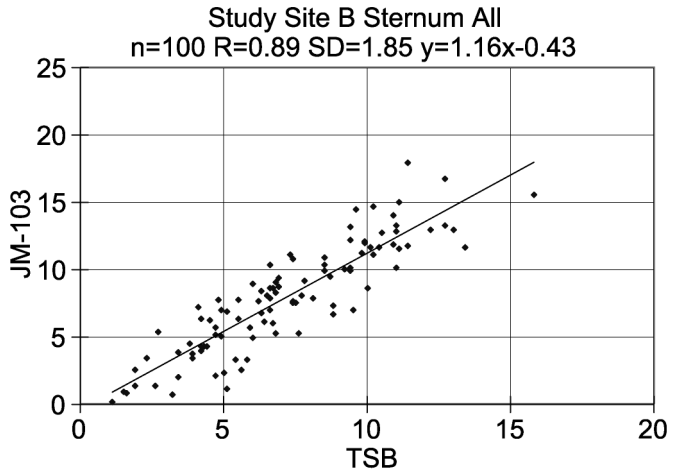
Graph 8 – Clinical Study Site A Other Patients, Sternum



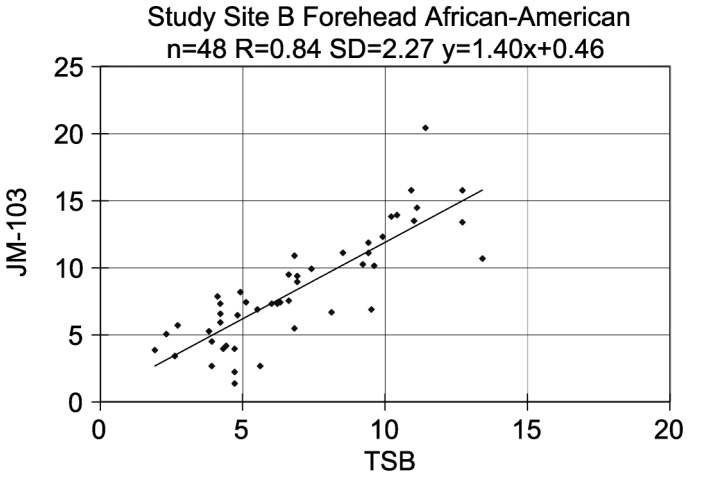
Graph 9 – Clinical Study Site B All Patients, Forehead



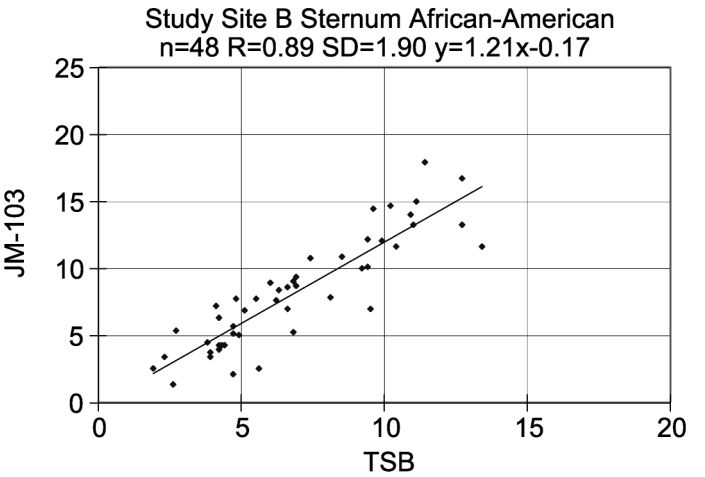
Graph 10 – Clinical Study Site B All Patients, Sternum



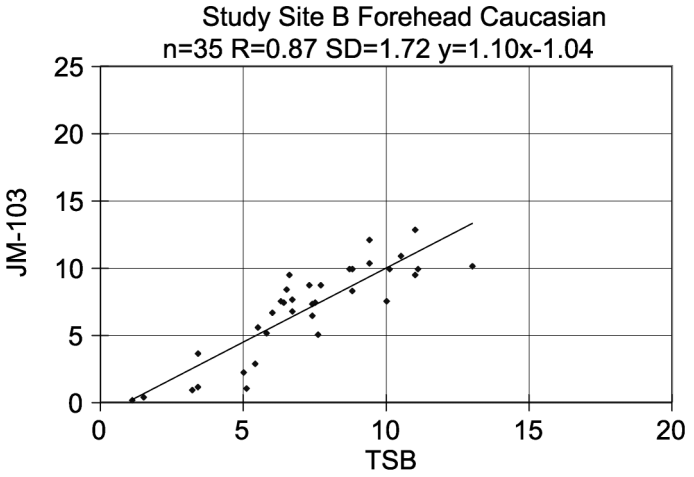
Graph 11– Clinical Study Site B African-American Patients, Forehead



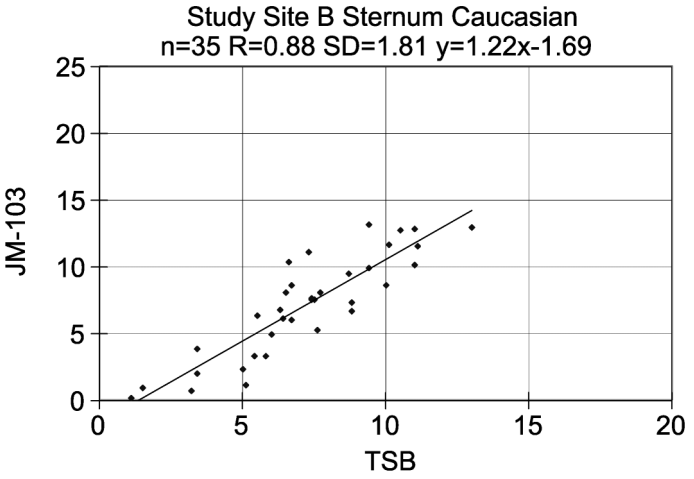
Graph 12 – Clinical Study Site B African-American Patients, Sternum



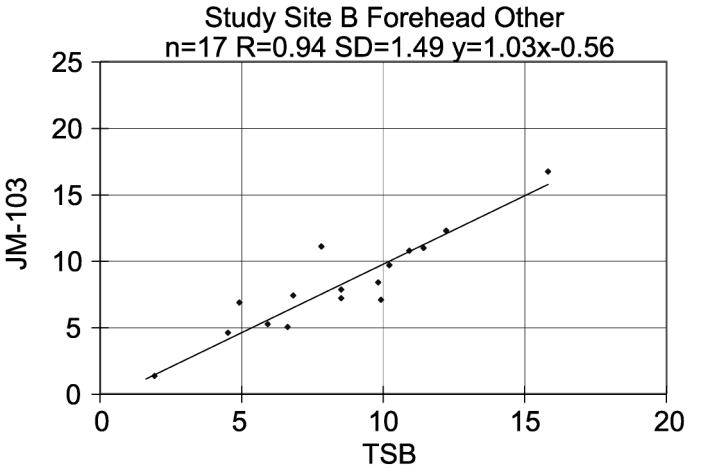
Graph 13 – Clinical Study Site B Caucasian Patients, Forehead



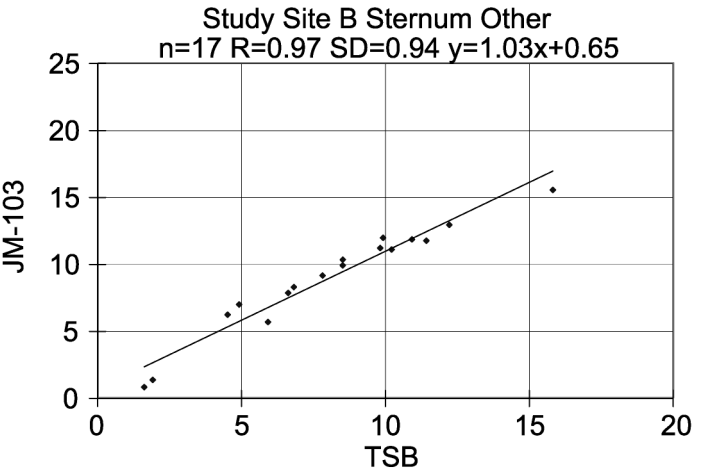
Graph 14 – Clinical Study Site B Causasian Patients, Sternum



Graph 15 – Clinical Study Site B Other Patients, Forehead



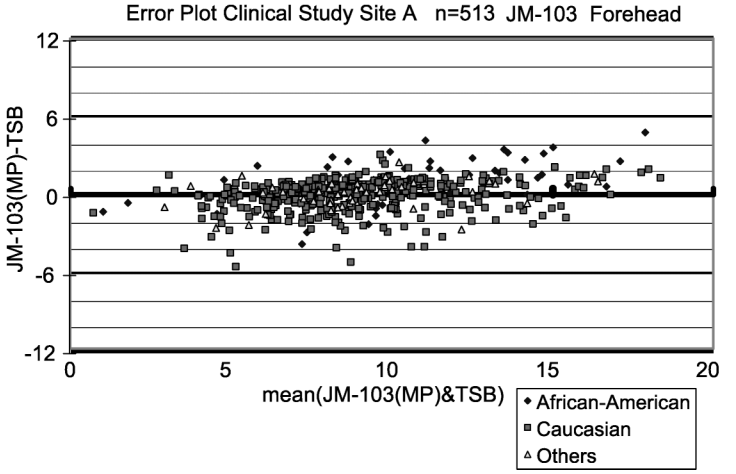
Graph 16 – Clinical Study Site B Other Patients, Sternum



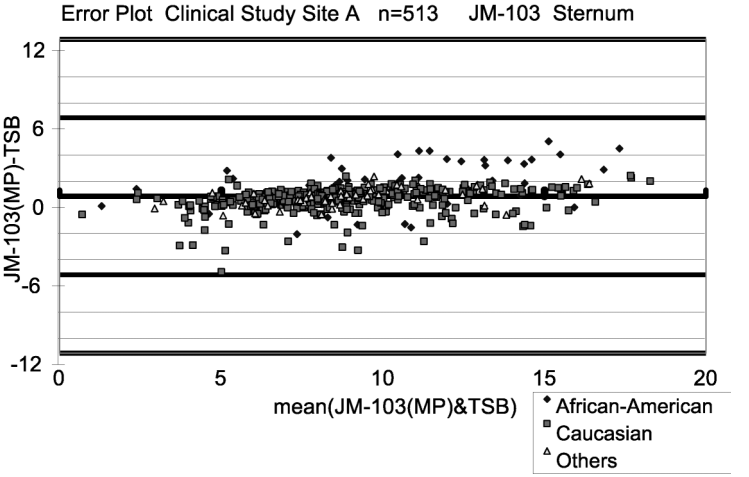
Graph 17 – Summary Table of Slope, Intercept, Standard Deviation, and Correlation Coefficients for Each Graph

Study site / patient population	Slope	Intercept	Correlation Coefficient (r)	Standard Deviation (RMSE)
SITE A Forehead All (n=513)	1.05	-0.35	0.914	1.29
SITE A Sternum All (n=513)	1.07	-0.74	0.946	1.02
SITE A Forehead African American (n=65)	1.15	-0.5	0.908	1.59
SITE A Sternum African American (n=65)	1.11	-0.4	0.908	1.55
SITE A Forehead Caucasian (n=399)	1.01	-0.1	0.916	1.2
SITE A Sternum Caucasian (n=399)	1.04	-0.6	0.956	0.88
SITE A Forehead Other (n=49)	1.06	-0.5	0.941	1.04
SITE A Sternum Other (n=49)	1.10	-1.0	0.977	0.65
SITE B Forehead All (n=100)	1.07	-0.00	0.84	2.14
SITE B Sternum All (n=100)	1.16	-0.43	0.89	1.85
SITE B Forehead African American (n=48)	1.40	+0.46	0.84	2.27
SITE B Sternum African American (n=48)	1.21	-0.17	0.89	1.9
SITE B Forehead Caucasian (n=35)	1.10	-1.04	0.87	1.72
SITE B Sternum Caucasian (n=35)	1.22	-1.69	0.88	1.81
SITE B Forehead Other (17)	1.03	-0.56	0.94	1.49
SITE B Sternum Other (17)	1.03	0.65	0.97	0.94

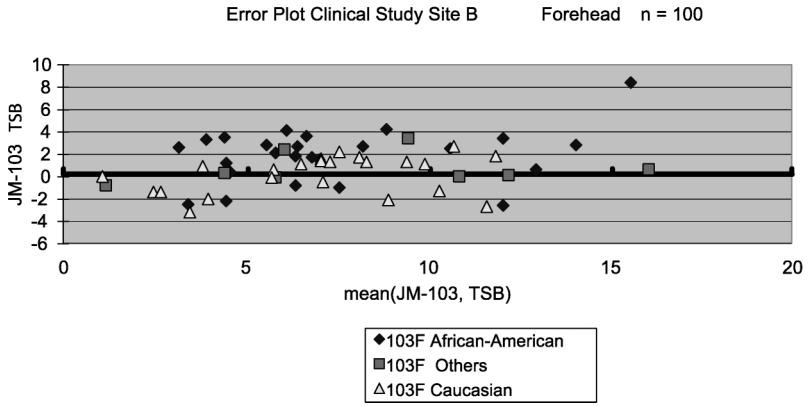
Graph 18 – Clinical Study Site A Error Plot, Forehead



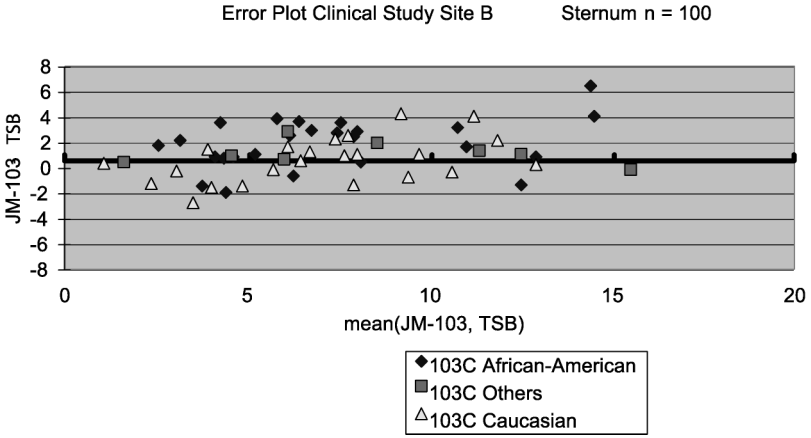
Graph 19 – Clinical Study Site A Error Plot, Sternum



Graph 20 – Clinical Study Site B Error Plot, Forehead



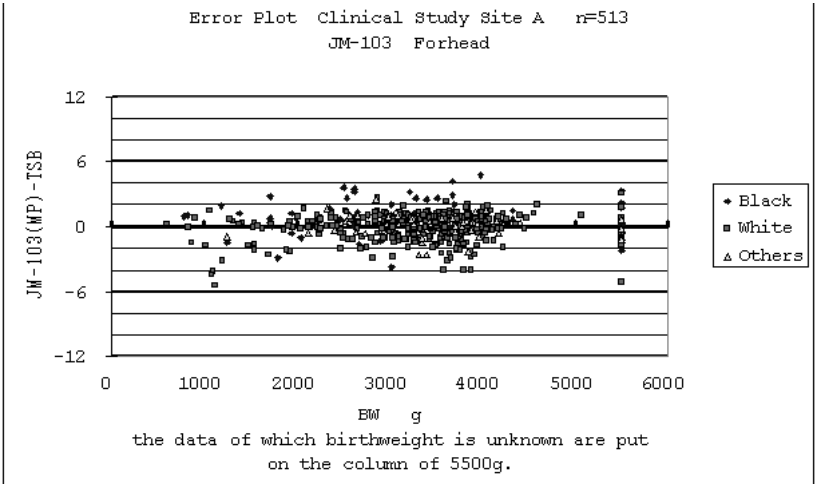
Graph 21 – Clinical Study Site B Error Plot, Sternum



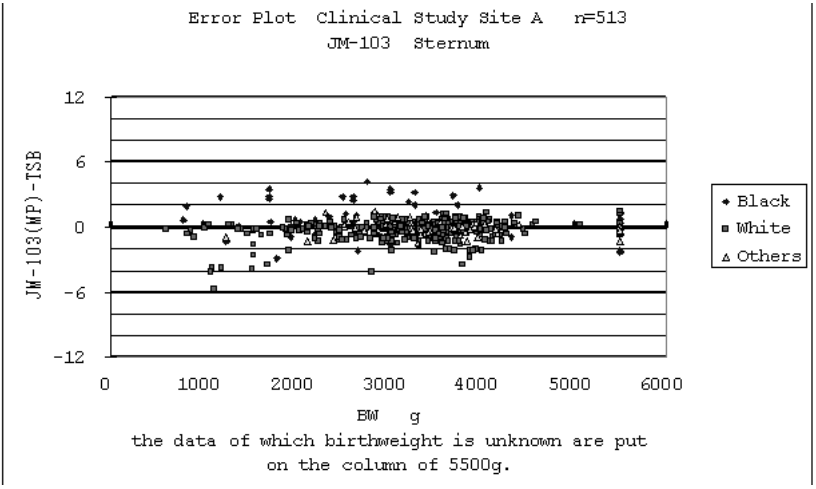
Graph 22 – Infant Weight Distribution

Infant Weight (grams)	Clinical Study A	Clinical Study B
Up to 999	6	2
1000 - 1499	15	0
1500 - 1999	23	13
2000 - 2499	37	23
2500 - 2999	68	19
3000 - and up	337	43
Unknown	27	0
Total	513	100

Graph 23 – Clinical Study Site A Birthweight Error Plot, Forehead



Graph 24 – Clinical Study Site A Birthweight Error Plot, Sternum



Reproducibility

Reproducibility of the light output of the device was tested daily using the checker. The checker determines the intensity of the light output of the device. The accuracy of the device is determined by how well the detectors in the unit measure the returning light. The results of the device testing using the checker show that the device produced output within the required range over the course of both clinical studies.

Reproducibility testing in the patient population can be derived from the data taken in Clinical study site A. The reproducibility data is based on 467 babies. Three independent measurements were taken at each site, forehead and sternum. Each measurement was recorded, the mean and standard deviation computed and recorded. The average standard deviation for forehead and sternum measurements was 0.3 for both.

Table 1: Reproducibility Data

Body Site	Deviation Range	Deviation Mean	Deviation Median	Mean Estimated Bilirubin Measurement Range (mg/dL)
Sternum	0.0 - 2.2	0.3	0.3	0.8 - 18.5
Forehead	0.0 - 2.6	0.3	0.2	0.1 - 19.5

Conclusion

What the data presented shows is that the JM 103 estimated bilirubin concentration measurement correlates to the serum bilirubin measurements. This data supports the use of this non-invasive device along with other clinical indicators as a aid in the management of jaundice in the neonatal patient population.

Appendix B
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